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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,611	10/06/2000	Maria Galanis	674537-2002	3929

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NEW YORK, NY 10151

EXAMINER

OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/623,611		GALANIS ET AL.	
	Examiner		Art Unit	
	ILIA OUSPENSKI		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4 - 9, 12 - 21, 28, 34, 35, and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-16 is/are allowed.
- 6) ☒ Claim(s) 2,4-9,12,13,17-21,28,34,35 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/06/2006 has been entered.

2. Applicant's amendments/remarks, filed 02/06/2006, are acknowledged.

Claims 1, 3, 10, 11, 22 – 27, 29 – 33, 36 – 37, and 39 – 41 have been cancelled previously.

Claim 2 has been amended.

Claims 2, 4 – 9, 12 – 21, 28, 34, 35, and 38 are pending.

3. Applicant's IDS, filed 02/27/2006, is acknowledged, and has been considered.

It is noted that the references where only the Abstract is in English have been considered only to the extent of the Abstract.

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4. This Office Action will be in response to applicant's amendment and arguments, filed 02/06/2006.

The rejections of record can be found in the previous Office Action, mailed 08/19/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

5. Claims 21 and 28 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from alternative features in the multiple base claims. See MPEP § 608.01(n). Applicant is invited to rewrite the claims in single dependent format.

Claim 21 is objected to because of the following informality: the word "immobilised" is apparently misspelled.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 17 is rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

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It is apparent that antibodies cAB-Lys3 and V86 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

It is noted that biological materials must be both known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. If Applicant or other members of the public were able to obtain the materials in question from a given depository or other source prior to and after the filing date of the application does not establish that upon issuance of a patent on the instant application such material would continue to be accessible to the public. Applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials from the depository or other source, nor is there any evidence as to the depository's policy regarding the material if a patent would be granted. Further, there is no assurance that the depository would allow unlimited access to the material if the application has matured into a patent. In the absence of evidence that the cAB-Lys3 and V86 antibodies are readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, the specification does not provide a sufficient enabling description of the claimed invention.

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8. Claim rejections under 35 USC 102(b) and 35 USC 103(a):

Claims 2, 7 – 9, 12 – 13, 20 – 21, 28, 34, 35, and 38 stand rejected under 35 U.S.C. 102(b) as being anticipated by Peach et al. (of record), and claims 2, 4 – 6, and 18 – 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Peach et al. in view of Koide (of record), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing, for the reasons presented by the Examiner during the interview with the Applicant on 03/01/2006.

During the interview, Applicant proposed to amend claim 2 as follows: the phrase "comprising at least one" has been replaced with: -- comprising within the VLD at least one -- .

The Examiner indicated that such amendment would be sufficient to overcome the rejections of record under 35 USC 102(b) and 35 USC 103(a).

In the absence of such amendment, the rejections of record are maintained for the reasons of record, as they apply to the amended claims. The rejections of record are incorporated by reference herein, as if reiterated in full.

9. Conclusion: claims 14 – 16 appear to be allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

April 14, 2006


PHILLIP GAMBEL, PH.D. J.D.
PRIMARY EXAMINER
Tech Center 1600
4/14/06